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December 16, 2005

Division of Dockets Management
Food and Drug Administration, Room 1061, (HFA-305)
5630 Fisher's Lane
Rockville, MD 20852

Docket Number 95S-0158 (BB IND #10,719)

RE: BB IND 10,719, POLY-SFH-P INJECTION [Polymerized Human Hemoglobin (Pyridoxylated), PolyHeme®], Protocol RTBSE-11-(N): Publicly Disclosed Information

Dear Sir:

Reference is made to our Investigational New Drug Application (IND) for Poly-SFH-P Injection for acute trauma, BB IND #10,719.

In conformance with 21 CFR 312.54(a) and the Draft Guidance for Industry entitled *Exception from Informed Consent Requirements for Emergency Research* (March 30, 2000) which require that Institutional Review Board (IRB) information concerning public disclosure be submitted to this Docket for clinical investigations involving an exception from informed consent [21 CFR 50.24(a)(7)(iii)], we provide documentation for the following sites in Salt Lake City, Utah:

University Health Care

University of Utah Institutional Review Board
75 South 2000 East, 512 RAB
Salt Lake City, Utah 84112

LDS Hospital Trauma Services

IHC Urban Central Region IRB
Office of Research
LDS Hospital
8th Avenue and C Street
Salt Lake City, UT 84143

A copy of this submission is being submitted to BB IND #10,719.

If you have any comments or questions, please contact the undersigned at 847-864-3500.

Sincerely,

Eva Essig, PhD
Vice President, Regulatory Affairs and Quality